

Attorney Docket No.: DRE-0057  
Inventors: Spotila, Loretta D.  
Serial No.: 09/856,937  
Filing Date: August 15, 2001  
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amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### **I. Priority Claim**

In accordance with the Examiner's suggestion, Applicants have amended the first sentence of the specification to include specific reference to the earlier filed application from which the instant application claims priority.

#### **II. IDS References**

The Examiner has advised the foreign patent documents AE and AF of the Information Disclosure Statement were not considered because Applicant did not provide copies of such documents. As acknowledged by the Examiner, however, copies of the GenCore sequence database entries from these patents were considered. As these entries comprise the relevant portions of these documents to the patentability of the instant invention, further consideration of the entire documents of AE and AF is not necessary.

#### **III. Rejection of Claims 1-4 under 35 U.S.C. § 112, first paragraph**

Claims 1-4 have been rejected under 35 U.S.C. § 112, first paragraph. The Examiner has acknowledged the specification to be

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enabling for methods and kits for identifying human individuals "at risk of developing osteoporosis" comprising steps/reagent for determining the identity of the nucleotides at positions 593, 598 and 620 of exon 10 of the tumor necrosis factor alpha 2 receptor gene. However, the Examiner suggests that the specification does not reasonably provide enablement for methods and kits for identifying osteoporosis risk in human comprising steps/reagents for detecting a polymorphism or genotype other than the particular exon 10 genotype set forth above.

Applicants respectfully traverse this rejection.

Contrary to the Examiner's suggestion, the specification provides detailed methods for assessing various polymorphisms in the tumor necrosis factor alpha 2 receptor gene, not simply polymorphisms at positions 593, 598 and 620 of exon 10. See specifically, see pages 5 and 6 of the specification wherein detection of polymorphisms in the microsatellite region of the tumor necrosis factor alpha 2 receptor gene are set forth. Also see Example 2 of the specification wherein specific reagents and steps used to detect polymorphisms in the microsatellite region of the tumor necrosis factor alpha 2 receptor gene are taught. Accordingly, the Examiner's suggestion that the specification is only enabling for steps/reagents for determining the identity of

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the nucleotides at positions 593, 598 and 620 of exon 10 of the tumor necrosis factor alpha 2 receptor gene is incorrect.

However, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to clarify that detection of a polymorphism of the TNFR2 gene (SEQ ID NO:1) is indicative of the human individual being at risk of developing osteoporosis. Claim 2 has been canceled in light of the amendments to claim 1. Further claims 3 and 4 have been canceled, thus mooted the rejection as it pertains to these claims.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

**IV. Rejection of Claims 1, 2 and 4 under 35 U.S.C. § 112, second paragraph**

Claims 1, 2 and 4 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner suggests that claims 1 and 2 are indefinite because it is unclear as to whether the claims are intended to be drawn to methods for identifying individuals at risk of developing osteoporosis as recited in the preamble or to

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methods of assessing the genotype of tumor necrosis factor alpha 2 receptor gene as recited in the final process step.

Accordingly, in an earnest effort to advance the prosecution of this case, and in accordance with the Examiner's suggestion, Applicants have amended claim 1 to clarify the relationship of detecting a polymorphism in the tumor necrosis factor alpha gene to the identification of individuals at risk of developing osteoporosis.

Claims 2 and 4 have been canceled by this amendment, thus mooting further rejections pertaining to these claims.

Withdrawal of these rejections under 35 U.S.C. § 112, second paragraph, is therefore respectfully requested.

**V. Rejection of Claims 3 and 4 under 35 U.S.C. § 102(b)**

Claims 3 and 4 have been rejected under 35 U.S.C. § 102(b) as being anticipated by the New England Biolabs 1992 catalog.

It is respectfully pointed out, however, that these claims have been canceled thus mooting this rejection.

Withdrawal of this rejection is therefore respectfully requested.

**VI. Conclusion**

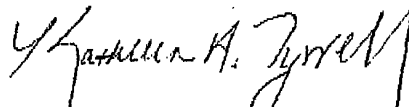
Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

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favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 2, 3 and 4 have been canceled without prejudice.

Claim 1 has been amended as follows:

1. (amended) A method for identifying human individuals at risk of developing osteoporosis comprising assessing the genotype of tumor necrosis factor alpha 2 receptor gene in a sample of DNA from an individual, wherein a polymorphism of the TNFR2 gene (SEQ ID NO:1) is indicative of the human individual being at risk of developing osteoporosis.